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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,314	03/14/2001	Randall W. Nelson	530-012	3078

7590 08/19/2002

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/19/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,314

Applicant(s)

NELSON ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, and 15-19 are drawn to a method for simultaneously determining whether a specimen contains any of one or more certain antigen species and a method for simultaneously determining whether a specimen contains any of one or more certain antibody species, classified in class 435, subclass 7.1.
 - II. Claims 4-14 and 20-28, drawn to a method for determining how much of one or more certain antigens are present in a specimen and a method for determining the amount of a certain antibody present in a specimen, classified in class 435, subclass 7.92.
 - III. Claims 29-30, drawn to a method of simultaneously determining whether an antibody population contained in a specimen contains one or more certain antibody species, classified in class 436, subclass 518.
2. Inventions I and II are distinct and independent inventions. Invention I is a method for simultaneously determining whether a specimen contains any of one or more certain antigen species or a method for determining whether a specimen contains any of one or more certain antibodies. Invention II is a method for determining how much of one or more certain antigens are present or a method for determining the amount of a certain antibody present in a specimen. Invention II involves the use of an

Art Unit: 1641

internal reference species and a means for capturing and isolating the internal reference species and also involves quantification of the antigen or antibody and Invention I does not require an internal reference species nor does Invention I require the step of quantification.

3. Inventions I and III are distinct and independent inventions. Invention I is a method for simultaneously determining whether a specimen contains any of one or more certain antigen species or a method for determining whether a specimen contains any of one or more certain antibodies. Invention III is a method for simultaneously determining whether an antibody population contained in a specimen contains one or more certain antibody species. Invention III involves the production of a post-combination affinity reagent and a screened preparation and involves separating the post-combination affinity reagent from the screened preparation to form an isolated post-combination affinity reagent. Invention III also involves adding a laser desorption/ionization agent. Invention I does not involve these limitations.

4. Invention II and III are distinct and independent inventions. Invention II is a method for determining how much of one or more certain antigens are present or a method for determining the amount of a certain antibody present in a specimen. Invention II involves the use of an internal reference species and a means for capturing and isolating the internal reference species and also involves quantification of the antigen or antibody and Invention III does not require an internal reference species nor does Invention I require the step of quantification. Also Invention III involves the production of a post-combination affinity reagent and a screened preparation and

Art Unit: 1641

involves separating the post-combination affinity reagent from the screened preparation to form an isolated post-combination affinity reagent. Invention III also involves adding a laser desorption/ionization agent. Invention II does not involve these limitations.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

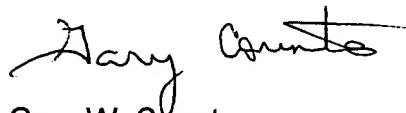
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts
Examiner
Art Unit 1641
August 9, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~/641